



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT

Assistant Commissioner for Patents
Washington, D.C. 20231

On _____

By: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Branscum, et al.

Application No.: 10/721115

Filed: November 24, 2003

For: Method and apparatus for evaluation
of sleep disorders

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

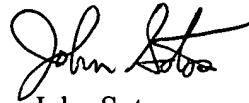
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Page 2

It is further noted that the categories provided for the information and references are not represented as being definitive and/or mutually exclusive. Additional categorizations are possible.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John Sotos", written in a cursive style.

John Sotos
Applicant

COIPE 35156
MAY 14 2004
U.S. PATENT & TRADEMARK OFFICE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

Application Number	10/721115
Filing Date	
First Named Inventor	
Art Unit	
Examiner Name	
Attorney Docket Number	

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	AA	US- 4,982,738	01-08-1991	Griebel	
	AB	US- 5,275,159	01-04-1994	Griebel	
	AC	US- 5,671,733	09-30-1997	Raviv	
	AD	US- 5,782,240	07-21-1998	Raviv	
	AE	US- 5,792,067	08-11-1998	Karell	
	AF	US- 5,797,852	08-25-1998	Karakasoglu	
	AG	US- 5,853,005	12-29-1998	Scanlon	
	AH	US- 5,879,313	03-09-1999	Raviv	
	AI	US- 5,961,447	10-05-1999	Raviv	
	AJ	US- 6,045,514	04-04-2000	Raviv	
	AK	US- 6,120,441	09-19-2000	Griebel	
	AL	US- 6,168,568	01-02-2001	Gavriely	
	AM	US- 6,171,258 B1	01-09-2001	Karakasoglu	
	AN	US- 6,201,982 B1	03-13-2001	Menkes	
	AO	US- 6,213,955 B1	04-10-2001	Karakasoglu	
	AP	US- 6,261,238 B1	07-17-2001	Gavriely	
	AQ	US-Application Ser. No. 040937		Westbrook	
	AR	US-			
	AS	US-			
	AT	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM- DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	AU							
	AV							
	AW							
	AX							
	AY							

Examiner
Signature

Date
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Unsaved Document

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

6

Complete if Known

Application Number

10/721115

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM- DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	AZ							
	BA							
	BB							

Examiner
SignatureDate
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Unsaved Document

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 6**Complete if Known**

Application Number	10/721115
Filing Date	
First Named Inventor	
Art Unit	
Examiner Name	
Attorney Docket Number	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BC	AASM (AMERICAN ACADEMY OF SLEEP MEDICINE TASK FORCE). Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep. 1999;22:667-689.	
	BD	A. BAR, et al. Evaluation of a portable device based on peripheral arterial tone for unattended home sleep studies. Chest. 2003;123:695-703.	
	BE	T. BOND. Evaluation and diagnosis of sleep-disordered breathing. Oral Maxillofacial Surg Clin N Am. 2002;14:293-296.	
	BF	C. BOOTH-THOMAS. The see-it-all chip. Time Magazine. 2003 Sept. 22;162(12). Downloaded as 5 pages from http://www.time.com/time/globalbusiness/printout/0,8816,485764,00.html on Oct. 22, 2003.	
	BG	R. CARTWRIGHT. What's new in oral appliances for snoring and sleep apnea: an update. Sleep Medicine Reviews. 2001;5:25-32.	
	BH	A.L. CHESSON, et al. Practice parameters for the indications for polysomnography and related procedures. Sleep. 1997;20:406-22.	
	BI	N.J. DOUGLAS. Home diagnosis of the obstructive sleep apnoea/hypopnoea syndrome. Sleep Med Rev. 2003;7:53-9.	
	BJ	R. FERBER, et al. Portable Recording in the Assessment of Obstructive Sleep Apnea. Sleep. 1994;17:378-392.	
	BK	K.A. FERGUSON. The role of oral appliance therapy in the treatment of obstructive sleep apnea. Clin Chest Med. 2003;24:355-364.	
	BL	W.W. FLEMONS. Home diagnosis of sleep apnea: a systematic review of the literature: an evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest. 2003;124:1543-79 and 14 pages of supplementary material published online.	
	BM	J.L. GOODWIN, et al. Feasibility of using unattended polysomnography in children for research -- report of the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Sleep. 2001;24:937-944.	
	BN	L. GROTE, et al. Therapy with nCPAP: incomplete elimination of sleep related breathing disorder. Eur Resp J. 2000;16:921-7.	
	BO	C.K. LI, W.W. FLEMONS. State of home sleep studies. Clin Chest Med. 2003;24:283-295.	
	BP	M.R. LITTNER, J.W. SHEPARD. Recommendations for research into measurement and classification of sleep disordered breathing: gazing into the crystal ball. Sleep. 1999;22:665-666.	
	BQ	N. MESLIER, et al. Validation of a suprasternal pressure transducer for apnea classification during sleep. Sleep. 2002;25:753-7.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Unsaved Document

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

4

of

6

Complete if Known

Application Number

10/721115

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BR	N. NETZER, et al. Overnight pulse oximetry for sleep-disordered breathing in adults: a review. Chest. 2001;120:625-633.	
	BS	P.E. PEPPARD, et al. Prospective study of the association between sleep-disordered breathing and hypertension. N Engl J Med. 2000;342:1378-1384.	
	BT	S.F. QUAN, J.C. GILLIN. New definitions of sleep disordered breathing -- not yet a mandate for change in clinical practice. Sleep. 1999;22:662.	
	BU	S.D. ROSS, et al. Systematic review and meta-analysis of the literature regarding the diagnosis of sleep apnea. Sleep. 2000;23:519-532.	
	BV	N. TACHIBANA, et al. A comparison of sleep laboratory activity in the United States and Japan. Sleep. 2002;25(Suppl.):A47.	
	BW	M-L. WALKER-ENGSTROM, et al. 4-year follow-up of treatment with dental appliance or uvulopalatopharyngoplasty in patients with obstructive sleep apnea. Chest. 2002;121:739-746.	
	BX	T. YOUNG, et al. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep. 1997;20(9):705-6.	
	BY	T. YOUNG, et al. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med. 2002;165:1217-1239.	
	BZ	CATEGORY 1 FOLLOWS: USE OF SNORING SOUNDS IN DETECTING SLEEP-DISORDERED BREATHING	
	BAA	J.H. FICKER, et al. Evaluation of a portable recording device (Somnocheck) for use in patients with suspected obstructive sleep apnoea. Respiration. 2001;68:307-12.	
	BBB	C.J. GRIFFITHS, et al. A video system for investigating breathing disorders during sleep. Thorax. 1991;46:136-140.	
	BCC	F.G. ISSA, et al. Digital monitoring of obstructive sleep apnea using snoring sound and arterial oxygen saturation. Sleep. 1993;16:S32.	
	BDD	F.G. ISSA, et al. Digital monitoring of sleep disordered breathing using snoring sound and arterial oxygen saturation. Am Rev Respir Dis. 1993;148:1023-1029.	
	BEE	A.W. McCOMBE, et al. An acoustic screening test for obstructive sleep apnea. Clinical Otology. 1995;20:348-351.	
	BFF	T. PENZEL, et al. MESAM: a heart rate and snoring recorder for detection of obstructive sleep apnea. Sleep. 1990;13:175-182.	

Examiner
Signature

Date

Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.
Unsaved Document

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

5

of

6

Complete if Known

Application Number	10/721115
Filing Date	
First Named Inventor	
Art Unit	
Examiner Name	
Attorney Docket Number	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BGG	Remmers sleep recorder, How to set up and use. Downloaded 2 pages on Oct. 31, 2003 from: www.comfortacrylics.com/appliance/resource/protocols/Remmers_instructions.pdf	
	BHH	Y. SIVAN, et al. Screening obstructive sleep apnoea syndrome by home videotape recording in children. Eur Respir J. 1996;9:2127-2131.	
	BII	Sleep Solutions Inc. NovaSom QSG Technology Summary. Downloaded 11 pages on July 21, 2002 from: http://www.sleep-solutions.com/phys/phys_novasom_qsg.htm	
	BJJ	SNAP Laboratories LLC. Downloaded 3 pages on July 21, 2002 from: (1) http://www.snaplab.com/home.htm (2) http://www.snaplab.com/mp_demo.htm (3) http://www.snaplab.com/mp_fact.htm	
	BKK	R. STOOHS, C. GUILLEMINAULT. Investigations of an automatic screening device (MESAM) for obstructive sleep apnea. Eur Respir J. 1990;3:823-829.	
	BLL	D.L. VAN BRUNT, et al. Intensity pattern of snoring sounds as a predictor for sleep-disordered breathing. Sleep. 1997;20:1151-1156.	
	BMM	J.E.S. WHITE, et al. The use of sound recording and oxygen saturation in screening snorers for obstructive sleep apnea. Clinical Otology. 1994;19:218-221.	
	BNN	CATEGORY 2 FOLLOWS: USE OF TRACHEAL BREATH SOUNDS IN DETECTING SLEEP-DISORDERED BREATHING	
	BOO	R.C. BECKERMAN, et al. Tracheal breath sounds for detection of apnea in infants and children. Critical Care Medicine. 1982;10:363-366.	
	BPP	J. CUMMISKEY, et al. The detection and quantification of sleep apnea by tracheal sound recordings. Am Rev Respir Dis. 1982;126:221-224.	
	BQQ	K.A. EAST, T.D. EAST. Computerized acoustic detection of obstructive apnea. Comput Meth Prog Biomedicine. 1985;21:213-220.	
	BRR	J.P. HEEMELS, et al. Tracheal sound detector. Med Biol Eng Comput. 1986;24:182-185.	
	BSS	W. HIDA, et al. Home sleep monitor for detecting apnea episodes by nasal flow and tracheal sound recordings. Tohoku J Exp Med. 1988;156(Suppl.):137-142.	
	BTB	W. HIDA, et al. Prevalence of sleep apnea among Japanese industrial workers determined by a portable sleep monitoring system. Respiration. 1993;60:332-337.	
	BUU	P.E. KRUMPE, J.M. CUMMISKEY Use of laryngeal sound recordings to monitor apnea. Am Rev Respir Dis. 1980;122:797-801.	

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Unsaved Document

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

6

of

6

Complete if Known

Application Number

10/721115

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BVV	R.P. MARSH, et al. Recorder for assessment of upper airway disorders. Otolaryngol Head Neck Surg. 1983;91:584-585.	
	BWW	N. MESLIER, et al. Tracheal sound recordings detect and quantify sleep apnea, hypopnea and snores. Am Rev Respir Dis. 1986;113:A55.	
	BXX	J. PEIRICK, J.W. SHEPARD Jr. Automated apnoea detection by computer: analysis of tracheal breath sounds. Med Biol Eng Comput. 1983;21:632-635.	
	BYV	W.P. POTSIC. Relief of upper airway obstruction by adenotonsillectomy. Otolaryngol Head Neck Surg. 1986;94:476-480.	
	BZZ	W.P. POTSIC. Comparison of polysomnography and sonography for assessing regularity of respiration during sleep in adenotonsillar hypertrophy. Laryngoscope. 1987;97:1430-1437.	
	BAAA	A. SANNA, et al. Interet su suivi des bruits respiratoires tracheaux dans le diagnostic de dysrythmies respiratoires nocturnes. Acta Clinica Belgica. 1991;46:159-164	
	BBBB	A.J. WILLIAMS, et al. A new computer program for storage and analysis of sleep study data. FASEB Journal. 1988;2:A1511.	
	BCCC		
	BDDD		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Unsaved Document